- 1. (cancelled).
- 2. (previously presented): A method according to claim 28, wherein step  $(\alpha)$  is carried out in an anhydrous medium.
- 3-5. (cancelled).
- 6. (previously presented): A method according to claim 28, wherein the nanodispersion comprises as component
- (a) a phospholipid, a hydrated or partially hydrated phospholipid, a lysophospholipid, or mixtures thereof.
- 7-15. (cancelled).
- 16. (currently amended): A <u>method according to claim 28, wherein the aqueous monodisperse</u>

  <u>nanodispersion of a lipophilic pharmaceutical active agent is a pharmaceutical liquid formulation in the form of an injectable solution, infusion solution, drops, spray, aerosol, emulsion, lotion, suspension, drinking solution, gargle or inhalant, which comprises a nanodispersion as defined in claim 29.</u>
- 17. (currently amended): A <u>method according to claim 28, wherein the aqueous monodisperse</u>

  <u>nanodispersion of a lipophilic pharmaceutical active agent is a pharmaceutical semisolid formulation in the form of an ointment, oil-in-water emulsion, water-in-oil emulsion, gel, lotion, foam, paste, suspension, ovula or plaster, which comprises a nanodispersion as defined in claim 29.</u>
- 18. (cancelled).
- 19. (currently amended): A <u>method according to claim 28, wherein the aqueous monodisperse</u> <u>nanodispersion of a lipophilic pharmaceutical active agent is a matrix- or membrane-controlled</u> pharmaceutical application system in the form of an oros capsule, transdermal system or injectable microcapsule, which comprises a nanodispersion as defined in claim 29.
- 20. (currently amended): A method according to claim 28, pharmaceutical formulation according to claim 16, wherein the nanodispersion is present in the aqueous phase.

21. (currently amended): A <u>method according to claim 28, pharmaceutical formulation according to claim 16,</u> wherein the nanodispersion is present in the aqueous phase in a concentration of 0.01 to 100 % by weight.

## 22-27. (cancelled).

- 28. (currently amended): A method of preparing a pharmaceutical formulation of a lipophilic pharmaceutical active agent in the form of an aqueous monodisperse nanodispersion having a Gaussian distribution, which steps consist essentially of
- $(\alpha)$  mixing the components
- (a) 0.1 to 30 % by weight of a phospholipid,
- (b) 1 to 50 % by weight of a polyoxyethylene coemulsifier selected from the group consisting of polyethoxylated fatty alcohols, polyethoxylated fatty acids, polyethoxylated vitamin E derivatives, polyethoxylated lanolin and derivatives thereof, polyethoxylated fatty acid partial glycerides, polyethoxylated alkylphenols, polyethoxylated fatty-alcohols and salts thereof, polyethoxylated fatty amines and fatty acid amides and polyethoxylated carbohydrates,
- (c) 0.1 to 80 % by weight of a lipophilic component which comprises a natural or synthetic or a partially synthetic C<sub>4</sub>-C<sub>18</sub>triglyceride, and a lipophilic pharmaceutical active agent, in which aqueous nanodispersion any pharmaceutically active agent is lipophilic and is always present in component (c), and
- (d) 0.63 to 14.2 % by weight of ethanol, with the proviso that the sum of (a), (b), (c) and (d) is 100 % by weight,

in conventional stirring apparatus until a homogeneous clear liquid is obtained, and

( $\beta$ ) adding the liquid obtained in step ( $\alpha$ ) to a water phase, wherein ( $\beta$ ) is carried out in the absence of high shear or cavitation forces, and wherein the particles in the nanodispersion have an average diameter <50 nm.

## 29. (cancelled).

30. (new): A method according to claim 28, wherein the polyoxyethylene coemulsifier is selected from the group consisting of polyethoxylated fatty alcohols, polyethoxylated fatty acids, polyethoxylated vitamin E derivatives, polyethoxylated lanolin and derivatives thereof, polyethoxylated fatty acid partial glycerides, polyethoxylated alkylphenols, and salts thereof.